K070156

Section 5 – Premarket Notification 510(k) Summary

SEP 26 2007

GENERAL INFORMATION:

Device Name and Classification

Product Name:	BioZ Dx Hemodynamic Monitor with 12-Lead ECG
Classification Name:	Plethysmography, Impedance
Common Name:	Impedance Cardiograph (ICG)
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.2770 (for ICG) and 21 CFR 870.2340 (for ECG)
Device Class:	II
Product Code:	74 DSB (for ICG) and 74 DPS (for ECG)

Manufacturer and Contact Person

CardioDynamics International Corporation
6175 Nancy Ridge Drive, # 300
San Diego, CA 92121 USA
Phone: 858-535-0202
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Paul L. Shaffer
Director, Quality and Regulatory

Date of Summary Preparation: January 15, 2007

SUBSTANTIAL EQUIVALENCE:

Predicate Devices:

K051228 – CardioDynamics BioZ® Dx Hemodynamic Monitor with Philips 12-Lead ECG
K011439 – CardioDynamics BioZ®.com Hemodynamic Monitor (for additional parameters)
K041434 – Analogic C3™ ICG Monitor (for additional parameters)
K010164 – GE Medical Systems ICG Module (for additional parameters)

Device Description:

This submission covers Version 4.0b5 of the BioZ Dx System Software for the BioZ Dx (K051228), which is a noninvasive impedance cardiography (ICG) device that provides hemodynamic parameters based on the measurement of thoracic electrical bioimpedance. The BioZ Dx measures this change in impedance by injecting a high frequency, low amplitude alternating electrical current through the thorax between a pair of sensors placed on the neck and another pair placed on the mid-axillary line at the xiphoid process level. By detecting and measuring the change in thoracic impedance as a function of time, the BioZ Dx is able to calculate stroke volume, cardiac output and many other hemodynamic parameters. The device additionally includes the capability of performing a standard 12-Lead ECG test.

The modified BioZ Dx software and firmware applies the same functions and scientific concepts as the predicate devices. Additional parameters have been added in this release that exists in the predicate devices, and a small number of routine software bugs were corrected with this release.

Intended Use:

The BioZ Dx device is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The device is intended to monitor hemodynamic parameters within hospitals and other healthcare facilities providing patient care. The modified BioZ Dx device has these same intended uses.

Additional parameter outputs are being displayed based on calculations incorporated into predicate CardioDynamic (Systemic Vascular Resistance Index and Left Cardiac Work Index), Analogic (Thoracic Fluid Content Index, Base Impedance, Heather Index, Q-C Interval & Stroke Index) and GE (Left Stroke Work Index) devices. These additional parameter calculations use measurements and/or parameters which already existed in the BioZ Dx predicate device.

Technology:

The modified BioZ Dx device has the same technological characteristics as the predicate BioZ Dx device. A human factors improvement has been made to the cable and electrode accessories whereby the connections with the dual element electrode and patient leadwires have unique connector fittings to further ensure proper connections. The accessory change was determined to be insignificant (not requiring a 510(k) submission), and was documented to file and implemented into the current BioZ Dx.

General Safety & Effectiveness Concerns:

The instructions for use for this device contain the necessary cautions and warnings to provide for safe and effective use for the device.

Risk management is an essential element of the design and development process, and hazard analysis assessments performed on the modified BioZ Dx device at the System and Software levels revealed that the enhancements present no additional risks from the predicate devices. The software hazard analysis for the modified device in included in section 16.1 and the system hazard analysis is included in section 18.1.

CardioDynamics International Corporation is presently certified to ISO13485:2003 by Nemko. No significant audit findings have been presented since initial ISO 13485 certification in May of 1998. All products are designed and manufactured under CDIC's Quality Management System, which includes Design Control and Good Manufacturing Practices.

Performance Testing:

There have been no hardware modifications between the modified BioZ Dx and the predicate BioZ Dx monitor device, thus the relevant electrical safety standards have not been impacted by this product change. The improvements to the cable/electrode accessories were confined to the patient sensor connector mechanism only, and there were no impacts to the electromagnetic compatibility standards when compared to the predicate BioZ Dx device.

Design Review is required, at a minimum, at the completion of each step in the design control process (i.e. Design Input, Design Output, Design Verification, Design Validation and Design Transfer). The design review process identifies the required deliverables for each step in the process and verifies the content and accuracy of each deliverable.

The following quality assurance measures were conducted for the modified BioZ Dx device and are included in this submission:

- Risk analysis
- Design requirements and traceability
- Unit and system level software and firmware verifications
- System level validations

The results of verification and validation tests concluded that the functionality and performance characteristics of the modified BioZ Dx are comparable to the currently marketed predicate devices.

Conclusion:

The results of all testing demonstrate that the modified BioZ Dx Hemodynamic Monitor with 12-Lead ECG do not raise any new issues of safety, effectiveness or performance of the device when compare to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2007

CardioDynamics International Corporation
c/o Mr. Paul L. Shaffer
Director, Quality and Regulatory
6175 Nancy Ridge Drive #300
San Diego, CA 92121

Re: K070156
Trade/Device Name: BioZ Dx Hemodynamic Monitor with Philips 12-lead ECG
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB and DPS
Dated: September 10, 2007
Received: September 12, 2007

Dear Mr. Shaffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070156

Device Name: **BioZ Dx HemoDynamic Monitor and Philips 12-lead ECG**

Indications For Use:

For the ICG function:

The BioZ Dx Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

Heart Rate (HR)
Systolic Blood Pressure (SBP)
Diastolic Blood Pressure (DBP)
Mean Arterial Blood Pressure (MAP)
Stroke Index (SI)
Stroke Volume (SV)
Cardiac Index (CI)
Cardiac Output (CO)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
Left Cardiac Work (LCW)
Acceleration Index (ACI)
Velocity Index or Index of Contractility (VI, IC)
Thoracic Fluid Content (TFC)
Base Impedance (TFI or Z_0)
Thoracic Fluid Content Index (TFCI)
Systolic Time Ratio (STR)
Systolic Time Ratio Index (STRI)
Pre-Ejection Period (PEP)
Left Ventricular Ejection Time (LVET)
Total Arterial Compliance (TAC)
Total Arterial Compliance Index (TACI)
Left Stroke Work Index (LSWI)
Heather Index (HI)
Q-C Interval (QC)
Left Cardiac Work Index (LCWI)
Electrocardiograph (ECG)
Systemic Stroke Resistance Index (SSRI or SSVRI)
End Diastolic Volume (EDV)
End Diastolic Index (EDI)

For the optional 12-lead ECG function:

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Gunnerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070156